

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
1240 Parklawn Dr.
Rockville, MD 20857

Date: 5/5/01

Re: 99P-1340/CP 1 — Petition to Have *Eternity* eau de parfum declared "Misbranded"

4384 01 MAY 16 A 9:38

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity* eau de parfum declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to fragrance products I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- | | | | |
|---|---|--|--|
| <input type="checkbox"/> anaphylaxis/shock | <input checked="" type="checkbox"/> double vision | <input checked="" type="checkbox"/> incoherence | <input type="checkbox"/> nausea |
| <input checked="" type="checkbox"/> anxiety, restlessness | <input type="checkbox"/> ear pain | <input type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input type="checkbox"/> asthma | <input type="checkbox"/> eczema | <input checked="" type="checkbox"/> irritability | <input type="checkbox"/> rashes |
| <input type="checkbox"/> breathing difficulty | <input type="checkbox"/> eyes, watery or dry | <input checked="" type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input type="checkbox"/> bronchitis | <input checked="" type="checkbox"/> fatigue | <input checked="" type="checkbox"/> laryngitis | <input checked="" type="checkbox"/> short-term mem. loss |
| <input checked="" type="checkbox"/> can't concentrate | <input checked="" type="checkbox"/> flushing | <input type="checkbox"/> lethargy | <input checked="" type="checkbox"/> sinusitis |
| <input type="checkbox"/> coughing | <input type="checkbox"/> headaches | <input checked="" type="checkbox"/> lymph nodes swell | <input type="checkbox"/> sneezing |
| <input type="checkbox"/> depression | <input type="checkbox"/> heart beat irregularity | <input type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input type="checkbox"/> disorientation | <input type="checkbox"/> hives | <input checked="" type="checkbox"/> muscle pain/weakness | <input type="checkbox"/> swallowing difficulty |
| <input type="checkbox"/> dizziness | <input type="checkbox"/> hypertension | <input type="checkbox"/> nasal congestion | <input checked="" type="checkbox"/> tinnitus |
| <input type="checkbox"/> other: _____ | | | |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Karen Bathrop - Karen Bathrop
your name

6200 Cannon/league Dr., Austin, TX 78745
address, city/st/zip

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and WRITE the FDA... today!

99P-1340

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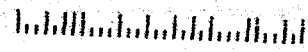
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THE NEW REACTOR

July - August 1999

